IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERNDISTRICT OF TEXAS
MARSHALL DIVISION

SHEILA RHYNE AND	**§**	
RANDALL RHYNE	**§**	
	§	
vs.	**§**	**CIVIL ACTION NO.**
	§	
BOSTON SCIENTIFIC CORPORATION	**§**	

PLAINTIFFS' ORIGINAL COMPLAINT

TO THE HONORABLE COURT:

Plaintiffs bring this Complaint against Defendant Boston Scientific Corporation for injuries sustained as a result of the wrongful conduct of Defendants as set forth herein. Plaintiff complains of Defendant and alleges on information and belief the following:

I. PARTIES

1. Plaintiff Sheila Rhyne is and at all times relevant to this Complaint was a citizen of the State of Texas.

2. Plaintiff Randall Rhyne is and at all times relevant to this Complaint was a citizen of the State of Texas.

3. Defendant Boston Scientific Corporation ("BSC") is a Delaware corporation with its corporate headquarters in Massachusetts. Defendant BSC may be served through its registered agent for service of process, Corporation Service Company d/b/a CSC-Lawyers Incorporating Service Company, 211 E. 7th Street, Suite 620, Austin, Texas 78701-3218.

II. JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332, because this is a civil action between citizens of different states and the matter in controversy exceeds the sum of $75,000.00, exclusive of interest and costs.

5. Venue is proper in this district pursuant to 28 U.S.C. § 1391 because defendant has sufficient contacts within the Eastern District of Texas such that it is subject to the Court's exercise of personal jurisdiction. At all times relevant hereto, Defendant designed, developed, manufactured, promoted, marked, distributed, tested, warranted and sold in interstate commerce the Transvaginal Mid-Urethral Sling System device in Texas, including within the Eastern District of Texas. In addition, Defendant employs multiple persons specifically to market, promote and sell its Transvaginal Mid-Urethral Sling products, including the Advantage Fit Sling System, to physicians and other health care providers located within the Eastern District of Texas. Defendant maintains such contacts within this district so as to subject it to personal jurisdiction.

6. Plaintiffs Sheila Rhyne and Randall Rhyne both reside in the Eastern District of Texas, Marshall Division. Moreover, the majority of the medical care and treatment required because of the harmful, deleterious, unreasonably dangerous, and unsafe effects of the product that forms the basis of this lawsuit was provided within the Eastern District of Texas.

III. FACTUAL ALLEGATIONS

7. BSC designs, manufactures, markets, packages, labels and sells medical devices, including a medical device known as the Advantage Fit sling (hereinafter "the Product"), a medical device implanted to treat certain women like Plaintiff for stress urinary incontinence.

8. Plaintiff Sheila Rhyne was implanted with a Product designed, manufactured, marketed, packaged, labeled sold, and placed in the stream of commerce by BSC. Due to defective design, defective manufacturing, defective marketing, and negligence by BSC, the Product has caused Plaintiff severe and permanent bodily injury and significant mental and physical pain and suffering, and economic losses.

9. The Product and the surgical mesh used to manufacture the Product have numerous defects that create a high risk of unreasonable and dangerous injuries and side effects with severe permanent adverse health consequences. These defects include, but are not limited to:

a. The material is not inert and therefore reacts to human tissue and/or other naturally occurring human bodily contents, adversely affecting patient health;

b. The mesh material harbors infections that adversely affect human tissue and patient health;

c. The Product and the mesh migrate from the location of their implantation, adversely affecting tissues and patient health;

d. The mesh material abrades tissue adversely affecting patient health;

e. The Product and the mesh regularly fail to perform the purpose of their implantation such that the patient requires removal of the device and repeated treatment and surgery;

f. Due to their various defects, the Product and the mesh regularly cause significant injury to patients such that the Product must be removed, resulting in additional surgery;

g. The Product and the mesh become embedded in human tissue over time such that if it must be removed due to its various defects, the removal damages others organ and tissues, adversely affecting patient health;

h. The Product is defective in its shape, composition, weight, physical, chemical and mechanical properties and is inappropriately engineered for use in the female pelvis.

10. Because of its numerous defects, the Product creates an unreasonable risk of injury and other adverse health consequences for patients, including, but not necessarily limited to, vaginal erosion, infection, extrusion, perforation, chronic pain and/or abscess.

11. Prior to the time that the Product was implanted in Plaintiff Sheila Rhyne's body, BSC was aware of numerous defects in the Product and the mesh, including but not limited to the defects and unreasonable risks in its product identified above. Despite being aware of the numerous defects and unreasonable risks identified above. Despite being aware of the numerous defects and unreasonable risks in its product identified above, BSC manufactured, marketed, and distributed the Product with the intent that it would be implanted in patients such as Plaintiff Sheila Rhyne. BCS was aware that implanting the Product in patients was likely to cause injury and harm to the patients into whom the Product was implanted despite its actual knowledge of the unreasonable risks identified above that resulted in significant and irreparable physical damage to the patient's body. Alternately, BSC failed to exercise reasonable care in determining the risks and potential adverse consequences of implanting the Product into patients.

12. BSC made public statements in the form of written product descriptions, product labels, promotional materials and other materials that asserted that implanting the Product in patient was reasonably safe and would not harm to patients. BSC made statements with the intent that medical professionals and members of the public would rely upon them, that members of the public would pay for the Product, and that medical professionals would implant the Product in patients. When BSC made these statements, BSC knew or, with reasonable inquiry, should have known that the statements were inaccurate.

13. BSC's employees, agents and/or representatives also made statements to numerous individuals, including medical professionals, that implanting the Product in patients was safe and

would not cause harm to patients. When BSC representatives made these statements, BSC knew or, with reasonable inquiry, should have known the statements were inaccurate.

14. BSC knowingly and deliberately made material misrepresentation(s) to the federal Food and Drug Administration concerning the design, manufacture, safety, and efficacy of the Product.

15. Before the Plaintiff suffered the injuries complained of herein, BSC was on notice of numerous bodily injuries caused by the Product, and based thereon, BSC knew or should have known that the Product caused an unreasonably high rate of vaginal erosion, infection, extrusion, perforation, chronic pain and/or abscess in women implanted with the Product.

16. Even though BSC has known or should have known that the Product created a foreseeable, unreasonable risk of harm to those women into whom it was implanted, BSC continued to market the Product in the United States. Defendant has sold thousands of units of the Product in the United States alone.

17. Defendants have never provided the federal Food and Drug Administration, the physicians who implanted the Product, or the parties in whom the Products is implanted within adequate warning or information of the risks that the Product causes an unreasonably high rate of vaginal erosion, infection, extrusion, perforation, chronic pain and/or abscess.

IV. COUNT 1-STRICT LIABILITY-DEFECTIVE MANUFACTURE

18. One or more of the defects in the Product is the result of improper or incorrect manufacturing processes that result in the Product as manufactured deviating from its intended design. These manufacturing defect(s) rendered the Product unreasonably dangerous to consumers and to Plaintiff. The defects in the Product implanted in Plaintiff existed from its manufacture; therefore the defects were present when it left the possession and control of BSC.

The Products defective manufacture is a producing cause of Plaintiff Sheila Rhyne's and Randall Rhyne's damages as described elsewhere herein.

V. COUNT II-STRICT LIABILITY-DEFECTIVE DESIGN

19. The Product is unreasonably dangerous and dangerously defective because as designed it has numerous defects that adversely affect patient health. The defects in the Product existed from its inception; therefore the defects were present when it left the possession and control of BSC. The foreseeable risks of harm posed by the design of the Product could have been reduced and/or avoided by the adoption of a reasonable alternative design by BSC. BSC's failure to adopt a safer alternative design of the Product is a producing cause of Plaintiff Sheila Rhyne's and Randall Rhyne's damages as described elsewhere herein.

VI. COUNT III-STRICT LIABILITY-MARKETING DEFECT

20. The Product was defective by reason of failure of BSC to provide adequate warnings and/or instructions.

21. Defendant failed to provide the kind of warnings and/or instructions that a manufacturer exercising reasonable care would have provided to physicians who implanted the Product or to those women who had been implanted with the Product concerning the following risks of which Defendant had actual or constructive knowledge at the time of the Product left Defendant's control:

a. The high failure rate of the product;

b. The high rate of infections and abscess caused by the product;

c. The high rate of vaginal erosions and extrusions caused by the product;

d. The high rate of chronic pain caused by the product;

e. The necessity to remove the Product from the patient's body in the event of product failure, infections, abscesses, erosions, or extrusion.

22. After receiving notice of numerous bodily injuries resulting from the Product, BSC failed to provide the kinds of post-marketing or post-sale warnings and/or instructions that a manufacturer exercising reasonable care should have provided to physicians who implanted the Product on those women who had been implanted with the Product that the product was causing an unreasonably high rate of infections, abscesses, erosions and/or extrusions. Furthermore, BSC failed to provide post-marketing or post-sale warning or instructions concerning the necessity to remove the Product from the patient's body in the event of product failure, infections, abscesses, erosion, or extrusion.

23. BSC's inadequate warnings and instructions, both at the time of marketing and after the sale of the Product are a producing cause of Plaintiff Sheila Rhyne's and Randall Rhyne's damages as described elsewhere herein.

VII. COUNT IV-NEGLIGENCE

24. BSC failed to exercise ordinary and reasonable care in designing, manufacturing, testing, marketing, labeling, packaging, selling and/or distributing the Product and BSC negligently failed to provide adequate warnings and instructions to Plaintiff or to her physician regarding the Product.

25. As a direct and proximate result of the negligence of BSC, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

VIII. COUNT V- BREACH OF WARRANTY

26. The Product implanted in Plaintiff failed to function as intended and as represented by BSC because it did not relieve the symptoms or otherwise alleviate the medical problems that it was intended to cure. Instead, the Product caused Plaintiff to suffer infection or inflammation, tissue abrasion, and other severe adverse health consequences. Accordingly, the Product was not

fit for the ordinary purpose for which such goods are used and failed to conform to the affirmations or representations of BSC. Furthermore, BSC knew that the Product was to be used for the particular purpose for which it was used on Plaintiff and knew that the expertise of BSC was relied upon to furnish suitable goods. Because the Product failed to conform to representations and was not suitable for the purpose for which it was used, BSC has breached express warranties, the implied warranty of merchantability, and the warranty of fitness for a particular purpose. As a result of BSC's breach of warranty, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

IX. DAMAGES

27. As a direct result of BSC's conduct, Plaintiff Sheila Rhyne suffered the following injuries and damages:

a. Medical expenses in the past and future;

b. Physical pain and mental anguish in the past and future;

c. Lost earnings in the past and loss of earning capacity in the future;

d. Physical disfigurement in the past and future; and

e. Physical impairment in the past and future.

f. As a direct result of BSC's conduct, Plaintiff Randall Rhyne suffered a loss of household services in the past and future.

X. PRAYER AND RELIEF

PREMISES CONSIDERED , Plaintiffs demand judgment on each of the causes of action alleged for the following relief:

A. Judgment in favor of Plaintiffs and against Defendants for damages in such an amounts as may be proven at trial;

B. Compensation for both economic and non-economic losses, described here in, in such an amount as may be proven at trial;

C. Punitive and/or exemplary damages in such an amount as may be proven at trial not to exceed the maximum amount permitted by law;

D. Attorney fees and costs;

E. Pre- and post-judgment interest; and

F. Such other and further relief to which Plaintiff may show themselves justly entitled, whether in law or equity.

Respectfully submitted,

/s/ M. RAYMOND HATCHER
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